REMARKS

Please reconsider the present application in view of the above amendments and the following remarks. Applicant thanks the Examiner for carefully considering this application.

Disposition of Claims

Claims 1-10 were pending in this application. By way of this reply, claims 3-10 have been canceled without prejudice or disclaimer. Further, new claims 11-18 have been added. Accordingly, Claims 1, 2, and 11-18 are now pending in this application. Of these claims, claim 1 is independent. The remaining claims are, directly or indirectly, dependent from claim 1.

Claim Amendments

By way of this reply, claims 3-10 have been canceled without prejudice or disclaimer. Further, claim 1 has been amended to clarify the invention. Further, new claims 11-18 have been added. New claims 11-18 are method claims, which include similar limitations to claims 1 and 2, and canceled claims 3-8, respectively. No new matter has been added by way of the amendments.

Specification Amendments

By way of this reply, the specification has been amended. Specifically, "4 hours" written as the gradual release period of HGF has been amended to be "4 weeks." Applicant notes that this amendment is made solely to correct an error appearing due to mistranslation

from Japanese to English. Support for this change can also be found in Figures 1-4, which show observation results for 4 weeks, not 4 hours. No new matter has been added by way of these amendments.

Rejection(s) under 35 U.S.C. §112

Claims 1-10 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the amendments to independent claim 1 in the reply to the Office Action dated July 30, 2007 introduces new matter because of the description in the paragraph [0057] of the specification is inconsistent with the claim as amended. As discussed above, the part, which is inconsistent with amended claim 1, was an erroneous description due to mistranslation from Japanese to English and, thus, by way of this reply, the paragraph [0057] of the specification has been amended to correct the error. Therefore, the specification and the drawings fully supports independent claim 1 as amended. Accordingly, the withdrawal of this rejection is respectfully requested.

Claims 1-10 stand rejected under 35 U.S.C. §112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, claim 1 is rejected as being indefinite, for failing to point out the conditions of gradual release of the HGF for about 4 weeks. As discussed above, claim 1 has been amended to clarify the feature of "gradual release of the HGF for about 4 weeks" as a feature of the gelatin hydrogel selected. Thus, amended claim 1 now clearly points out the subject matter, which Applicant regards as the invention. Claims 3-10 are also rejected as being indefinite, because, since they are drawn to a composition, it is unclear how the intended use

would alter the composition. As discussed above, claims 3-10 have been canceled without prejudice or disclaimer. New claims 13-18, which are drawn to methods for treating cardiomyopathy, include substantially the same intended use as that recited in the canceled claims 3-10, respectively. Thus, with regard to claims 3-10, the rejection is now moot. New claims 13-18 clearly points out the subject matter, which Applicant regards as the invention. Accordingly, the withdrawal of this rejection is respectfully requested.

Rejection(s) under 35 U.S.C. § 102

Claims 1-10 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Circulation, 106, supplement, p II-350, Nov., 2002, Meeting abstract ("Tambara"). By way of this reply, claims 3-10 have been canceled. Thus, with regard to claims 3-10, this rejection is now moot. With regard to claims 1 and 2, independent claim 1 has been amended in this reply. Thus, to the extent that this rejection now applies to independent claim 1 as amended, the rejection is respectfully traversed for the following reasons.

As previously discussed, independent claim 1 includes, in part, a limitation of "*gradually releases HGF for about 4 weeks*," and Applicant respectfully asserts that Tambara fails to teach or suggest the limitation of the claimed invention.

One or more embodiment in the present invention is directed to cardiomyopathy therapeutic agent containing hepatocyte growth factor (HGF) and gelatin hydrogel, that gradually releases the HGF. As a result of conducting extensive studies on therapeutic agents for dilated cardiomyopathy, the inventors of the present invention found a cardiomyopathy therapeutic agent containing HGF and gelatin hydrogel that can gradually releases HGF for a

long period. Experimental results in the application demonstrate the gradual release of HGF from the agent continues over 4 weeks, and aggressive therapeutic effects continue for the same period (see, paragraphs [0058]-[0065] in the published application). Accordingly, amended claim 1 requires, in part, a limitation of "*gradually releases HGF for about 4 weeks.*"

In contrast, Tambara discloses a controlled release of HGF via gelatin hydrogel sheets. However, the gelatin hydrogel in Tambara is capable of releasing HGF for only two weeks, because the gelatin hydrogel in Tambara is prepared by chemically bridging the gelatin as a matrix, and in this case, degradation time of the gelatin hydrogel is dependent on the level of chemical bridge.

In other words, the cardiomyopathy therapeutic agent having the feature of the agent that "*gradually releases HGF for about 4 weeks,*" as required by the claimed invention, has been uniquely developed and selected by the present inventor so as to advantageously treat cardiomyopathy. Tambara neither teaches nor suggests composition of any agent with capability of such a long term release of HGF, nor is it intended to treat cardiomyopathy.

Accordingly, Tambara does not disclose or suggest at least "*gradually releases HGF for about 4 weeks,*" as recited in claim 1. Thus, independent claim 1 is patentable over Tambara. Dependent claim 2 is also patentable for at least the same reasons. Therefore, withdrawal of this rejection is respectfully requested.

New claims

Of new claims 11-18, claim 11 depends from claim 1 and includes all the limitations of claim 1. As discussed above, amended claim 1 is patentable over Tambara. Accordingly, new claim 11 is patentable for at least the same reasons as set forth above. Further, new claims 12-18 are, directly or indirectly, dependent on claim 11. Accordingly, new claims 12-18 are patentable for at least the same reasons as set forth above. Thus, entry and favorable consideration of the new claims is respectfully requested.

Conclusion

Applicant believes this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 17195/006001).

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Respectfully submitted,

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